

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/56

Issued: 29 October 2004

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION REQUEST	



NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE

	Section
<p><b>Medical Device/Equipment:</b> BD Vacutainer<sup>®</sup> SST<sup>™</sup>, SST II<sup>™</sup>, and SST II Advance<sup>™</sup> blood collection tubes (glass and plastic).</p>	▶ ①
<p><b>Problem:</b> Incorrect test results (positive and negative bias) when using BD Vacutainer<sup>®</sup> SST<sup>™</sup>, SST II<sup>™</sup> and SST II Advance<sup>™</sup> blood collection tubes with specific named test systems. Following the issue of MDEA/2004/055 on 14 October 2004, new information has been provided by the manufacturers.</p>	▶ ②
<p><b>Action by:</b></p> <ul style="list-style-type: none"> <li>• Consultant Clinical Biochemists</li> <li>• Consultant Haematologists</li> <li>• Laboratory Managers</li> </ul>	▶ ③
<p><b>Action:</b> Note that these recommendations update advice given in MDEA(NI)2004/55 issued on 14 October 2004.</p> <p>– Laboratory staff should contact the manufacturers of blood collection tubes and test systems for updated information on affected blood collection tube/test system combinations. In light of this information, patient recall or retesting may need to be considered.</p>	▶ ④
<p><b>Distributed by NIAIC to:</b></p> <p>Chief Executive of each HSS Board Chief Executive of each HSS Trust</p> <p>Chief Executive of each Agency NIAIC Liaison Officers</p> <p><b>For onward distribution see Section 5</b></p>	▶ ⑤
<p><b>Contacts</b> Details of manufacturer/supplier contacts, MHRA and NIAIC contacts.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b> Report suspect test results from blood samples collected in BD Vacutainer<sup>®</sup> blood collection tubes to Becton Dickinson, the test system manufacturer and NIAIC.</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

BD Vacutainer<sup>®</sup> SST<sup>™</sup>, SST II<sup>™</sup>, and SST II Advance<sup>™</sup> blood collection tubes (glass and plastic).

## 2. PROBLEM:

Following publication of MDEA(NI)2004/55, MHRA has received from the manufacturers updated information relating to the incorrect results which may be generated when using Vacutainer<sup>®</sup> SST<sup>™</sup>, SST II<sup>™</sup> and SST II Advance<sup>™</sup> blood collection tubes in combination with some test systems (see MDA/2004/048).

Appendices 1 & 2 of MDEA(NI)2004/55 referenced the CA15-3 assay for use on the Bayer test systems as being affected. Bayer has informed MHRA that the 'BR' assay is affected by this issue. The Bayer 'CA15-3' assay is **not** affected by this issue.

## 3. ACTION BY:

- Consultant Clinical Biochemists
- Consultant Haematologists
- Laboratory Managers

## 4. ACTION:

- Laboratory staff should contact BD Preanalytical Systems and the named test system manufacturers to obtain the latest information regarding the use of SST<sup>™</sup>, SST II<sup>™</sup> and SST II Advance<sup>™</sup> blood collection tubes with the particular test system.
  - Note the amended contact details for BD Preanalytical Systems in the Contacts section.
- Laboratory staff may wish to request from the manufacturer information and data required to support their recommendations.

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Clinical Governance Leads
- Clinical Directors
- Supplies Staff (RSS)
- Nursing Directors
- Medical Directors
- Directors of Pathology
- Pathology Managers
- Medical Oncologists
- Radiation Oncologists
- Consultant Biochemists
- Consultant Haematologists
- Consultant Physicians
- Endocrinologists
- Phlebotomists
- Biochemistry Laboratories
- Chemical Laboratories
- Haematology Laboratories
- Immunology Laboratories
- Microbiology Laboratories
- Independent Health and Social Care Providers – Private Clinics through HSS Board R&I Units

## 6. CONTACTS:

BD Preanalytical Systems  
Customer Services Team  
21 Between Towns Road  
Cowley  
Oxford  
OX4 3LY

Tel: 01865 781 699  
Fax: 01865 781 627  
E-mail: [bdukvacutainer@europe.bd.com](mailto:bdukvacutainer@europe.bd.com)

Immunochemistry Support  
Bayer plc  
Bayer House  
Strawberry Hill  
Newbury  
Berkshire RG14 1JA

Tel: 01635 566 222 (option 3)  
Fax: 01635 566 274  
E-mail: [immunochem.helpdesk@bayer.co.uk](mailto:immunochem.helpdesk@bayer.co.uk)

Adam Roberts  
Beckman Coulter  
Oakley Court  
Kingsmead Business Park  
London Road  
High Wycombe  
Buckinghamshire  
HP11 1JU

Tel: 01494 429 192  
Fax: 01494 429 182  
E-mail: [aroberts@beckman.com](mailto:aroberts@beckman.com)

Patrick Ford  
Euro/DPC Ltd  
Glyn Rhonwy  
Llanberis  
Gwynedd  
LL55 4EL

Tel: 01286 871 871  
Fax: 01286 871 802  
E-mail: [patrick.ford@dpconline.com](mailto:patrick.ford@dpconline.com)

Enquiries to the MHRA should quote reference number **2004/008/031/061/008** and be addressed to:

### Technical aspects:

Dr Khalid Razak or Ms Andrea Molyneaux  
Medicines & Healthcare products Regulatory  
Agency  
Hannibal House  
Elephant and Castle  
London SE1 6TQ

Tel: 020 7972 8200 / 8119  
Fax: 020 7972 8106

E-mail: [khalid.razak@mhra.gsi.gov.uk](mailto:khalid.razak@mhra.gsi.gov.uk)  
[andrea.molyneaux@mhra.gsi.gov.uk](mailto:andrea.molyneaux@mhra.gsi.gov.uk)

### Clinical aspects:

Mr Jonathan Plumb  
Medicines & Healthcare products Regulatory Agency  
Hannibal House  
Elephant and Castle  
London  
SE1 6TQ

Tel: 020 7972 8128  
Fax: 020 7972 8103

E-mail: [jonathan.plumb@mhra.gsi.gov.uk](mailto:jonathan.plumb@mhra.gsi.gov.uk)

Enquires to NIAIC should quote reference number **MDEA(NI)2004/56** and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868

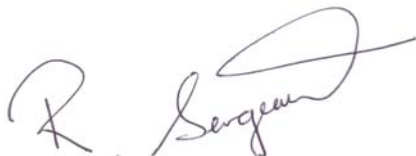
Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## **7. FEEDBACK:**

Report suspect test results from blood samples collected in BD Vacutainer® blood collection tubes to Becton Dickinson, the test system manufacturer and NIAIC.

Robert Sergeant  
Operational Manager NIAIC

A handwritten signature in black ink, appearing to read 'R. Sergeant', is positioned below the printed name and title.

### **HOW TO REPORT ADVERSE INCIDENTS**

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2004/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*